

U.S.S.N. 09/247,406

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AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

drawn to a method of treating; Group IX, claims 61-78, drawn to a method of identifying fusion proteins; and Group X, claims 79-88, drawn to a method of identifying fusion protein that has reactivity other than an antibody.

In response, applicant elects Group I, claims 1-28, with traverse.

2. The Office Action also required election of a species from among enzyme, receptor, anticancer, immunosuppressive, immunostimulatory, antibiotic, antiviral, and trophic activity in claims 14 and 87. In response, applicant elects immunostimulatory activity as the species for initial examination, with traverse.

3. Applicant initially notes that the Office Action fails to set forth any reasoning to support the conclusion that "Inventions I, VII, VIII, IX, and X are unrelated." Contrary to the suggestion of the Office Action, the methods claimed in Groups I, VII, IX, and X are substantially the same. Each involve the same basic steps and processes. Thus, the main claim in each group (claims 1, 46, 61, and 79) share the following basic procedure:

Providing a collection of mutant polypeptides wherein the amino acid sequence of each mutant polypeptide differs in at least one position from a polypeptide of interest, and

identifying those mutant polypeptides within the collection that (1) *have an alteration in an immune response compared to the polypeptide of interest*, and (2) retain at least one desired characteristic.

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The claims differ only in the exact formulation of the difference in the immune response (italicized section above) and the addition of some limitations (none of which affect the main process steps listed above). None of the differences in claims 1, 46, 61, and 79 cause the methods to be independent. For example, the claims formulate the alteration in immune response in the following ways:

Claim 1: "have an alteration in antibody reactivity compared to the polypeptide of interest,"

Claim 46: "exhibit less of, or have less potential to exhibit, an allergic response than the polypeptide of interest,"

Claims 61 and 79: "exhibit less of, or have less potential to exhibit, at least one undesirable immune response than the polypeptide of interest."

All of these are just examples of the same general concept: alteration in an immune response. For example, claim 4 (depending from claim 1) limits the antibody reactivity to antibody reactivity associated with an undesirable immune response (see language of claims 61 and 79 above). Similarly, an allergic response (claim 46) is an undesirable immune response (claims 1 [see claim 4], 61, 79). Thus, none of the differences in language of this clause of the claims renders the claims "independent."

The added limitations also fail to make the claimed methods independent. Claims 1 and 79 merely provide more specificity to the step of identification of mutant polypeptides (see last paragraph in claims 1 and 79). Since such specific manipulations can be used with the methods

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of claims 46 and 61, they can hardly be said to make the various methods independent. Claim 46 is limited to allergens as the polypeptide of interest. Since the polypeptide of interest in claims 1, 61, and 79 can be allergens this feature also fails to make the claims independent. Similarly, the limitation of claim 61 to use of a fusion polypeptide as the polypeptide of interest fails to render the claims independent since claims 1, 46, and 79 can also use a fusion polypeptide.

MPEP § 806.04, cited in the Office Action, provides the following relevant example of independent inventions:

Two different combinations, not disclosed as capable of use together, having different modes of operation, different functions or different effects are independent.... A process of painting a house and a process of boring a well would be [an] example.¹

Applicants submit that the present Groups I, VII, IX, and X fail to come close to this standard of independence. Accordingly, applicant respectfully requests joinder and examination of Groups I, VII, IX, and X, claims 1-28, 46-53, and 61-88.

Applicants also traverse the restriction requirement as currently set forth for the following reasons. To be valid, a restriction requirement must establish both that (1) the "inventions" are either independent or distinct, and (2) that examination of more than one of the "inventions" would constitute a burden to the Examiner. No showing or discussion of any burden is set forth

¹ This is the passage paraphrased in the Office Action.